REMARKS/ARGUMENTS

In view of the foregoing amendments and following remarks, favorable reconsideration of the pending claims is requested.

Status of the Claims

Claims 1-25 are under examination.

Claim 1 has been amended to clarify that the excluded fraction at the end of the chromatography is characterized by the absence of intact *Bifidobacterium* cells.

Rejections under 35 USC § 112

The Examiner has maintained the rejections of Claims 1-25 under 35 U.S.C. § 112, first paragraph, as being non-enabled. As noted in the previous response, the microorganism in question has been deposited under the Budapest treaty, and a statement by Applicants' representative, Timothy Balts, has been submitted showing that the deposits fully meet the requirements of 37 CFR §§ 1.806-808.

However, the Examiner now asserts that the statement with respect to the deposit of the biological sample is not persuasive because the Applicant has not provided a copy of the deposit receipt and/or contract with the depository for deposit and maintenance of the deposit. Applicant respectfully submits that statement by Applicant's representative is sufficient to fulfill the requirements with respect to 35 U.S.C. § 112. In this regard, the Examiner's attention is drawn to 37 CFR §§ 1.806-809, which clearly sets forth that the statement by the Applicant's representative is sufficient to overcome this rejection. No further documentation is necessary. However, in the interest of expediting prosecution, Applicant has proved herewith a Deposit receipt for *Bifidobacterium breve* strain deposited under the number I-2219 with the CNCM.

In view of the above statements and deposit receipt, Applicant submits that the rejection under 35 U.S.C. § 112 has been overcome.

Prior Art Rejections

Claims 1-25 have rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Publication 2008/0268099 to Blareau, or by U.S. Patent 7,410,653, also to Blareau, and the rejection of Claims 1-25 under 35 U.S.C. § 102(b) as being anticipated by WO 01/01785 to Blareau. WO 01/01785 is the PCT equivalent U.S. Patent 7,410,653.

Applicant respectfully submits that the cited art fails to disclose or suggest each and every element of the claims and therefore the cited art does not anticipate or render obvious the claimed invention. In particular, Applicant submits that the cited art does not disclose or suggest the recited immunomodulatory product. More specifically, the cited art does not teach a step in which the *Bifidobacterium* is removed from the aqueous substrate, and as such the prior art teaches a composition that includes the *Bifidobacterium* In contrast, the claimed invention teaches removal of the *Bifidobacterium*, which results in a immunomodulatory product free of intact *Bifidobacterium* cells. To emphasize this significant distinction, Claim 1 has been amended to recite that the excluded fraction at the end of the chromatography is characterized by the absence of intact *Bifidobacterium* cells.

At the outset, it is important to note that US 2008/0268099 (Blareau et al.) describes an immunomodulatory product obtained by the bioconversion of a milk substrate with the aid of *Bifidobacterium breve* strain 1-2219. The immunomodulatory product described in Blareau et al. comprises the substrate used to culture the bacteria *Bifidobacterium breve* 1-2219 mixed with said *Bifidobacterium breve* I-2219. In other words, Blareau necessarily teaches a culture that includes *Bifidobacterium breve* I-2219. Notably, Blareau does not disclose or suggest the step of removing the bacteria or the step of extracting a specific fraction of the obtained culture broth.

The present invention is directed to an immunomodulatory product obtained by the incubation of the same bacteria, *Bifidobacterium breve* strain 1-2219, on a aqueous substrate comprising lactoserum permeate, lactoserum protein hydrolyzate and lactose, and then removing the bacteria and extracting a specific fraction (exclusion fraction obtained from a gel exclusion chromatography having an exclusion threshold of 600 kDa) of the aqueous substrate obtained after incubation. This necessarily results in a product/composition that is different than the cited art.

As discussed in Applicant's previous response, the method described by Blareau uses a different substrate than the method of the present invention and, based on the example 2 of the present Application which shows the major influence of the substrate's composition on the composition of the obtained fraction, that because these substrates for culturing *Bifidobacterium breve* strain 1-2219 are different, the obtained immunomodulatory products are necessarily

different. Thus, the products described in the Blareau reference are different than the claimed immunomodulatory product.

In addition, Applicants have previously explained that the immunomodulatory product according to the claimed invention distinguishes from the product of Blareau by (i) the use of a different substrate that necessarily leads to different products; (ii) the removal of the *Bilidobacierium breve* strain 1-2219 and (iii) the extraction of a specific fraction after exclusion gel exclusion chromatography having an exclusion threshold of 600 kDa.

Based on these explanations, the immunomodulatory product according to the present invention distinguishes from the product described in Blareau in that they are objectively and factually different. Accordingly, the immunomodulatory product recited in Claim 1 is different than that of Blareau and as such is novel and not anticipated.

In view of the clear language of the claim and Applicant's explanations, it is surprising that the Examiner is under the belief that immunomodulary product according to the present invention still comprises *Bilidobacterium breve* strain I¬2219 (see page 11 of the Office Action). In view of this misunderstanding, the Applicant has amended Claim 1 to clarify that the resulting immunomodulatory product is free of intact *Bifidobacterium* cells. Applicant believes that this amendment should alleviate any concern the Examiner may have regarding the claimed invention being identical to that disclosed in the cited art.

Since the Applicant has put forth a sufficient explanation as to why the claimed invention is different and not identical to that of the cited art, no additional evidence is necessary to show that they are not identical. As noted above, the clear difference in the process of making the recited immunomodulatory product necessarily results in a product that is different from that described in the Blareau references. Further, the amendment to claim 1 clearly distinguishes the claimed invention from the product of Bleareau.

Once again, it is clear from the above that immunomodulatory product according to the present patent application is different, and thus novel over US 2008/0268099 and US 7,410,653.

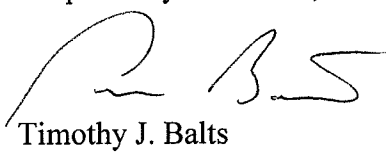
Double Patenting Rejection

Applicant requests that the Examiner continue to hold the double patent rejection in abeyance until after the prior art rejections have been overcome.

In view of the foregoing amendments and remarks, it is respectfully submitted that the rejections under 35 U.S.C. § 102and 112 have been overcome, and that the pending claims are in condition for immediate allowance.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,



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TRAITE DE BUDAPEST SUR LA RECONNAISSANCE
INTERNATIONALE DU DEPOT DES MICRO-ORGANISMES
AUX FINS DE LA PROCEDURE EN MATIERE DE BREVETS

FORMULE INTERNATIONALE

DESTINATAIRE :

Compagnie Gervais Danone
BP 63 - 126 rue Jules Guesde
92302 Levallois-Perret

NOM ET ADRESSE
DU DEPOSANT

RECEPISSE EN CAS DE DEPOT INITIAL, délivré en vertu de la règle 7.1 par l'AUTORITE DE DEPOT INTERNATIONALE identifiée au bas de cette page

Copy of the Original Receipt
certified by
Dr Georges WAGENER
Director of the CNCM

July 10, 2000

C.N.C.M. COLLECTION NATIONALE DE CULTURES DE MICROORGANISMES Institut Pasteur

I. IDENTIFICATION DU MICRO-ORGANISME	
Référence d'identification donnée par le DEPOSANT : **DN-156007**	Numéro d'ordre attribué par l'AUTORITE DE DEPOT INTERNATIONALE : **I - 2219**

II. DESCRIPTION SCIENTIFIQUE ET/OU DESIGNATION TAXONOMIQUE PROPOSEE

Le micro-organisme identifié sous chiffre I était accompagné :

EPO - DG 1
09. 11. 2005
123

■ d'une description scientifique

■ d'une désignation taxonomique proposée

(Cocher ce qui convient)

III. RECEPTION ET ACCEPTATION

La présente autorité de dépôt internationale accepte le micro-organisme identifié sous chiffre I, qu'elle a reçu le **31 MAI 1999** (date du dépôt initial) [1]

IV. RECEPTION D'UNE REQUETE EN CONVERSION

La présente autorité de dépôt internationale a reçu le micro-organisme identifié sous chiffre I le (date du dépôt initial)
et a reçu une requête en conversion du dépôt initial en dépôt conforme au Traité de Budapest le (date de réception de la requête en conversion)

V. AUTORITE DE DEPOT INTERNATIONALE

CERTIFIÉ CONFORME
A L'ORIGINAL
CNCM
Collection Nationale de Cultures de Microorganismes

Nom et adresse : COLLECTION NATIONALE DE CULTURES DE MICROORGANISMES (C. N. C. M.) INSTITUT PASTEUR 28, Rue du Docteur Roux 75724 PARIS CEDEX 15

Signature(s) de la (des) personne(s) compétente(s) pour représenter l'autorité de dépôt internationale ou de l'(des) employé(s) autorisé(s) : Mme Y. CERISIER
Directeur Administratif de la CNCM

Date : Paris, le 28 juin 1999

1 En cas d'application de la règle 6.4.d), cette date est la date à laquelle le statut d'autorité de dépôt internationale a été acquis.

Formule BP/4 (page unique)

BP-4TB.FRA